

REMARKS

Entry of the foregoing, reexamination and further and favorable reconsideration of the subject application, in light of the following remarks, pursuant to and consistent with 37 C.F.R. § 1.114, are respectfully requested.

I. Claim Amendments

By the foregoing amendment, claims 1 and 18 have been amended to recite "bronchial asthma due to the accumulation of eosinophiles in cells, tissues or a body[.]" Support for this amendment can be found throughout the originally filed application. Claim 19 has also been amended to become dependent on independent Claim 18, instead of being dependent on independent Claim 1. Further, claim 3 has been canceled without prejudice or disclaimer to the subject matter recited therein. Applicant reserves the right to file one or more divisional and/or continuation applications directed to any of the canceled subject matter. No new matter has been introduced by way of the above amendments.

II. Response to Rejections Under 35 U.S.C. §§ 102 and 103

(a) Claim 3 has been rejected under 35 U.S.C. § 102(b) as purportedly being anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Nair et al. (WO 01/15553). This rejection is respectfully traversed. Nevertheless, to expedite prosecution in the present application, and not to acquiesce to the Examiner's rejection, Claim 3 has been canceled without prejudice or disclaimer to the subject matter recited therein. Since the Examiner's rejection is now rendered moot, withdrawal of such rejection is respectfully requested.

(b) The Examiner has maintained the rejection of claims 1, 7-8, and 17 and newly rejected claims 18-19 under 35 U.S.C. § 103(a) as purportedly being unpatentable over Kim et al. (1999) and Assem (1973). This rejection is respectfully traversed.

Initially, Applicant notes that claims 7-8 were previously canceled without prejudice or disclaimer to the subject matter recited therein. *See* AMENDMENT AND REPLY DATED FEB. 7, 2007, at 4. Thus, the Examiner's rejection as to claims 7-8 is moot.

As to independent claims 1 and 18, and dependent claims 17 and 19, respectively, Applicant submits that the combination of the Kim et al. reference with the Assem reference fails to teach or suggest the claimed invention that is directed to a method for treating bronchial asthma and symptoms of bronchial asthma "due to the accumulation of eosinophiles in cells, tissues or a body, comprising administering an effective amount of black rice extract to an individual in need thereof." Claims 1 and 18 (emphasis added). In fact, in the Office Action dated June 9, 2008, the Examiner admitted that the combination of the Kim et al. and Assem references "do not teach that the bronchial asthma is due to the accumulation of eosinophiles" OFFICE ACTION DATED JUNE 9, 2008, at 9, ll. 4-5.

As shown in Example 3 and Figure 2 of the present application, the inventor has discovered that the accumulation of eosinophiles in airway of mice was inhibited by administration the pelargonidin component of black rice extract. This result would not have been expected nor would it have been obvious to one of ordinary skill in the art based on the combination of the Kim et al. and Assem references. This is because, contrary to the Examiner's comments, bronchial asthma due to the accumulation of eosinophiles is a different process belonging to late phase reaction ("LPR") than bronchial asthma due to immediate-type allergy to various allergens belonging to early-phase reaction ("EPR"). The references cited by the Examiner teach bronchial asthma due to immediate-type allergy to

various allergens. Since the pharmacological mechanism of the two types of bronchial asthma are different, commercially available drugs used today to treat EPR bronchial asthma and LPR bronchial asthma are different. *See* AMENDMENT AND REPLY DATED FEB. 7, 2008, at 9, l. 19-10, l. 11. EPR depends largely on the release of mediators from airway mast cells. On the other hand, LPR and the concomitant increases in airway reactivity are associated with an influx and activation of inflammatory cells like eosinophiles in the bronchial mucosa. *Id.*

The Kim et al. reference teaches that the methanol extract of *Oryza sativa* L. subsp. Hsien Ting possesses strong anti-anaphylactic activity by inhibition of histamine release from mast cells. Given the different processes and mechanisms involved in bronchial asthma due to the accumulation of eosinophiles (*e.g.*, LPR), one of ordinary skill in the art would not have had a reasonable expectation of success in utilizing antihistamines or an inhibitor of anaphylactic mechanisms for treatment of bronchial asthma due to the accumulation of eosinophiles.

Moreover, as discussed above, neither the Kim et al. reference nor the Assem reference teach or suggest treating bronchial asthma due to accumulation of eosinophiles. Rather, the Assem reference teaches treatment of bronchial asthma due to immediate-type allergy to various allergens (*e.g.*, EPR), not bronchial asthma due to accumulation of eosinophiles (*e.g.*, LPR). Thus, the Assem reference is essentially treating a different condition from that claimed in the present application. Thus, even if the Kim et al. reference is combined with the Assem reference, one of ordinary skill in the art would not have arrived at Applicant's claimed invention.

In view of the above, one of ordinary skill in the art would not have had a reasonable expectation of success in practicing the invention as currently claimed based upon the

teachings of the Kim et al. and Assem references. As such, a proper *prima facie* case of obviousness has not been established. Therefore, the Examiner is respectfully requested to withdraw this rejection under 35 U.S.C. § 103(a).

CONCLUSION

In view of the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order. Such action is earnestly solicited.

In the event that there are any questions relating to this Amendment and Reply, or the application in general, it would be appreciated if the Examiner would telephone the undersigned attorney concerning such questions so that prosecution of this application may be expedited.

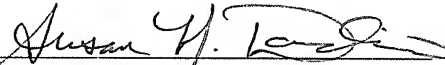
The Director is hereby authorized to charge any appropriate fees that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800.

Respectfully submitted,

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